REMARKS/ARGUMENTS

In response to the Office Action of November 14, 2003, Applicants request re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Claim Status/Support for Amendments

Claim 42 has been amended. Claims 2-35 were cancelled in a previous response(filed on June 13, 2003). The Examiner has acknowledged that claims 1, 36 and 39 are drawn to allowable subject matter. Claims 1 and 36-43 remain pending in the instant application.

No new matter has been added by the amendments to the specification made herein.

In the "Background of the Invention" section a punctuation error was corrected at page 1, line 21.

The description of the reference at page 4 has been amended to correct a typographical error in the international application number. The corresponding international publication number has also been added.

The "Description of the Figures" section has been amended for consistency of language in the figure descriptions.

The paragraph at page 21, beginning at line 7, has been

amended to correct typographical errors.

The protocol at page 21, beginning at line 12, has been amended to correct typographical errors and to properly identify trademark names by capitalization.

The paragraph at page 22, beginning at line 2, has been amended to properly identify trademark names by capitalization.

The paragraph at page 22, beginning at line 19, has been amended to properly identify trademark names by capitalization.

The protocol at page 24, beginning at line 1, has been amended to correct typographical errors, punctuation errors, and to properly identify trademark names by capitalization.

The paragraph at page 24, beginning at line 15, has been amended to properly identify trademark names by capitalization.

The paragraph at page 27, beginning at line 6, has been amended to identify the name AMICON by capitalization. It is uncertain whether AMICON is an actual trademark or the name of a corporation since it has been cited as both.

In the "Detailed Description" section, the term "cerebrospinal fluid" has been added to define the abbreviation "CSF" at page 28, line 15 in order to provide explicit support for cerebrospinal fluid as recited in claim 38. "CSF" is a well known abbreviation for cerebrospinal fluid in the biochemical art. A typographical error within the same paragraph has also been amended (skill

replaced skilled).

The abstract has been amended to remove the legal phraseology "said".

No new matter has been added by the amendment to claim 42 made herein.

Claim 42 (depends upon claim 41) has been amended to provide proper antecedent basis for the term "diagnostic kit" as recited in claim 41.

Rejections under 35 USC 112, first paragraph

Claims 37, 38 and 40-43, as presented on June 13, 2003, stand rejected under 35 USC 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time that the application was filed, had possession of the claimed invention.

The Examiner indicates that this is a new matter rejection.

The Examiner asserts that claim 37 recites the limitation wherein "the sample is an unfractionated body fluid or a tissue sample" which is considered to be new matter. The Examiner acknowledges that Applicant discloses "unfractionated body fluids or tissue sample" (page 11, lines 1-9); however the disclosure is directed to the deficiencies of retentate chromatography not the

instant claimed invention. Therefore, it is suggested by the instant specification that the "unfractionated body fluids or tissue sample" limitation is what is know in the art; however, it has never been contemplated to be the claimed subject matter.

Applicants respectfully disagree with the Examiner's assertion that the limitation "the sample is an unfractionated body fluid or a tissue sample" constitutes new matter.

It has been established that by disclosing in a patent application a device that inherently performs a function or has a property, or operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter (see MPEP 2163.07(a)).

Applicants contend that SELDI MS operates upon the principles of retentate chromatography which involves the use of unfractionated body fluids or tissue samples. The practice of SELDI MS is part of the claimed methods.

The Examiner asserts that the "unfractionated body fluids or tissue sample" limitation is disclosed in the instant specification with reference to the prior art only and not to the claimed subject matter. The specification discloses, at page 10, lines 16 and 17,

that SELDI MS operates upon the principles of retentate chromatography. Retentate chromatography is limited by the use of unfractionated body fluids and tissue samples (page 11, lines 1-9). The claimed methods are carried out through the use of SELDI MS (see page 19, lines 6-7 and page 20, lines 2-4; for example). Thus, considering that retentate chromatography uses unfractionated body fluids and tissue samples and SELDI MS is based upon principals of retentate chromatography, the use of unfractionated body fluids or tissue samples is inherently encompassed within the practice of SELDI MS.

Accordingly, contrary to the Examiner's assertion, the "unfractionated body fluids or tissue sample" limitation as recited in claim 37 does not constitute new matter.

The Examiner asserts that the limitation "cerebrospinal fluid" as recited in claim 38 is considered to be new matter.

Applicants respectfully disagree with the Examiner's assertion that the limitation "cerebrospinal fluid" constitutes new matter.

It has been established that the mere inclusion of dictionary or art recognized definitions known at the time of filing of an application would not be considered new matter (see MPEP 2163.07 I).

Applicants contend that the terms "cerebrospinal fluid" and "CSF" are equivalent terms used interchangeably in the art.

Cerebrospinal fluid is commonly referred to by the abbreviation "CSF". The dictionary reference of cerebrospinal fluid also includes the abbreviation "CSF" (see attached definition as accessed from the web site dictionary.com; labeled reference 1). One of skill in the art would understand that the abbreviation "CSF" refers to cerebrospinal fluid; even when the abbreviation is used alone (for example, see attached US Patent 6,066,163 which uses the abbreviation in both the claims (claim 15) and the specification; column 2, line 23; labeled reference 2).

Accordingly, contrary to the Examiner's assertion, the "cerebrospinal fluid" limitation as recited in claim 38 is both a dictionary and an art-recognized definition which was known at the time of filing of the instant application and thus does not constitute new matter.

The Examiner asserts that the limitation "wherein said patient is a human" as recited in claim 40 is considered to be new matter. The Examiner acknowledges that Applicant discloses "the peptide fraction in human blood" (page 5, lines 18-23) however, the disclosure is directed to the method of Richter et al. but not the instant method of the claimed invention. Therefore, it is suggested by the instant specification that the "wherein said patient is a human" limitation is what is known in the art; however it has not been contemplated to be the claimed subject matter.

Applicants respectfully disagree with the Examiner's assertion that the limitation "wherein said patient is a human" constitutes new matter.

It is clear that the discussion of Syndrome X at page 15, line 4 to page 17, line 6 of the instant specification refers to human patients; see especially page 15, lines 5-6; "a large segment of the adult population of industrialized countries develops this metabolic syndrome". Additionally, the table shown in Figure 1 is clearly charting data obtained from human patients.

Accordingly, contrary to the Examiner's assertion, considering that the specification is clear regarding the practice of the claimed methods using samples obtained from human patients, the "wherein said patient is a human" limitation as recited in claim 40 does not constitute new matter.

The Examiner asserts that the limitation "diagnostic kit with defined composition such as SEQ ID NO:1 and antibody" is considered to be new matter. The Examiner acknowledges that Applicant discloses "a diagnostic kit" (page 18, lines 5-7); however, the disclosure does not disclose that said diagnostic kit comprises SEQ ID NO:1 or antibody.

Applicants respectfully disagree with the Examiner's assertion that the limitation "diagnostic kit with defined composition such as SEQ ID NO:1 and antibody" constitutes new matter.

Page 28, lines 1 to page 33, line 2 of the instant specification discloses a discussion of immunoassays and their reagents, i.e. antibodies, which can be used to determine the presence of the disease specific marker (SEQ ID NO:1, disclosed at page 27). Page 28, line 1-8, clearly indicates that if a skilled artisan had possession of the disease specific marker (SEQ ID NO:1)he/she would be able to raise antibodies which are useful in diagnostic methods and devices. Page 18, lines 5-7 discloses that an objective of the invention is to teach a diagnostic kit for determining the presence of the disease specific marker. In other words, the diagnostic kit is comprised of elements used to carry out the claimed methods, i.e. determining the presence of the disease specific marker, SEQ ID NO:1.

Applicants respectfully contend that the elements for carrying out the disclosed methods are clearly disclosed and further contend that it is clear that SEQ ID NO:1 is the disease specific marker disclosed in the instant application and further one of skill in the art would recognize that antibodies can be used to determine the presence of the disease specific marker, i.e. SEQ ID NO:1.

Accordingly, contrary to the Examiner's assertion, the "diagnostic kit with defined composition such as SEQ ID NO:1 and antibody" limitation as recited in claims 41-43 does not constitute new matter.

Applicants have now shown that they had possession of the invention, as defined by the claims recited herein, at the time that the application was filed and thus respectfully request that the rejections under 35 USC 112, first paragraph be withdrawn.

CONCLUSION

In light of the foregoing remarks, amendments to the specification and amendment to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,

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Examiner copy
reference # 1

cerebrospinal fluid
n. Abbr. **CSF**

The serumlike fluid that circulates through the ventricles of the brain, the cavity of the spinal cord, and the subarachnoid space, functioning in shock absorption.

* 25 accessed from dictionary.com